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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 10/791,209 | 03/01/2004 | Soonkap Hahn | 81671 | 3988 |
| 22242 | 7590 | 10/13/2006 | EXAMINER | |
| FITCH EVEN TABIN AND FLANNERY 120 SOUTH LA SALLE STREET SUITE 1600 CHICAGO, IL 60603-3406 | | | SKOWRONEK, KARLHEINZ R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/791,209 | HAHN, SOONKAP |
| | Examiner | Art Unit |
| | Karlheinz R. Skowronek | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-17 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>20050925;20040519;20040514</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Karlheinz R. Skowronek whose telephone number is (571) 272-9047.

Election/Restrictions

- I. Claims 1-17, are drawn to methods of detecting STR, classified in class 435, subclass 6.
- II. Claims 18-21, are drawn to kits for the detection of STR, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case detection of STRs can be accomplished by southern blotting or PCR-followed by gel electrophoresis.

Searching for methods of detecting STR would not necessarily result in art on kits to detect STR, and vice -versa. Searching the art for both inventions would result in a search burden for the office.

2. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
4. During a telephone conversation with James Schuman on June 28, 2006 a provisional election was made without traverse to prosecute the invention of group 1, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 09-26-2005, 05-19-2004, 05-14-2004 was filed after the mailing date of the application on 03-01-2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantial" in claims 1, 3, 7 and 15 is a relative term, which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification

does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what substantial means. Are 10 bp, 100 bp, or 1000 bp substantial? Claims 2-13 are also rejected because they depend from claim 1, and thus contain the above issues due to said dependence. Claims 16-17 are also rejected because they depend from claim 15, and thus contain the above issues due to said dependence.

It is unclear what "FRAXA" means in claims 1, 3, 7, and 14. The term "FRAXA" is not defined by the claims or the specification. In some instances the art defines "FRAXA" as a genetic locus on the X chromosome and in other instances "FRAXA" is defines the FMR1 gene. Thus in the instant case, the use of "FRAXA" is vague. Claims 2-13 are also rejected because they depend from claim 1, and thus contain the above issues due to said dependence.

Claim 16 is vague with regards to the step in which the hybridizing takes place. Since claim 15, from which claim 16 depends, contains multiple hybridization steps and multiple hybridization targets, the recitation of "the hybridization target for the STRs is unclear.

Similarly, the STR probe of claim 16 is also vague.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Beattie et al. (US Pat 6,268,147 B1).

Claim 15 is directed to a method of detecting a short tandem repeat polymorphism involving obtaining genomic DNA, PCR amplification of the DNA of interest, obtaining a single stranded product from the PCR, hybridizing a colorimetric labeled oligonucleotides to the single stranded product, binding the labeled hybrid to a solid phase, separating the labeled products from the remainder of the product; recovering the labeled product, hybridizing the labeled target to a microarray, measuring the colorimetric intensities of the hybridized labeled product, and comparing the results with known control samples to quantify the results.

Beattie et al. teach a method for analyzing Short Tandem Repeat Polymorphism markers in genomic DNA by amplifying obtained genomic DNA by PCR (col. 20, line 7-8), hybridizing a colorimetric labeled oligonucleotides to the single stranded product, binding the labeled hybrid to a solid phase, separating the labeled products from the remainder of the product, recovering the labeled product (col. 29, lines 35-45), hybridizing the labeled target to a microarray (col. 29, lines 52-56), measuring the colorimetric intensities of the hybridized labeled product, and comparing the results with known control samples to quantify the results (col. 30, line 21-24 and col. 62, lines 13-21).

Regarding claim 16, Beattie et al. teach a marker of 10 repeat units that has been labeled with a stacking probe (col. 37, line 58-60) hybridized to a capture probe of

length 4 repeats. The target of the instant claim is being interpreted to be a probe that is part of the microarray and the probe is being interpreted as the nucleic acid that results from steps a-g of claim 15. Thus, the marker of Beattie et al. reads on the STR probe of the instantly claimed invention and capture probe reads on the target of the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie et al. (US Pat 6,268,147 B1), and further in view of Oostra et al. (Cytogenetic and Genome Research, Vol. 99, Iss. 1-4, p. 257-264, 2002).

Claim 1 is directed to a method of detecting a mutation indicative of fragile X syndrome involving obtaining genomic DNA, PCR amplification of the DNA of the X chromosome, obtaining a single stranded product from the PCR, hybridizing a colorimetric labeled oligonucleotides to the single stranded product, binding the labeled hybrid to a solid phase, separating the labeled products from the remainder of the product; recovering the labeled product, hybridizing the labeled target to a microarray, measuring the colorimetric intensities of the hybridized labeled product, and comparing the results with known control samples to quantify the results.

Beattie et al. teach a method for analyzing Short Tandem Repeat Polymorphism markers in genomic DNA by amplifying obtained genomic DNA by PCR (col. 20, line 7-8), hybridizing a colorimetric labeled oligonucleotides to the single stranded product, binding the labeled hybrid to a solid phase, separating the labeled products from the remainder of the product, recovering the labeled product (col. 29, lines 35-45), hybridizing the labeled target to a microarray (col. 29, lines 52-56), measuring the colorimetric intensities of the hybridized labeled product, and comparing the results with known control samples to quantify the results (col. 30, line 21-24 and col. 62, lines 13-21).

Beattie et al do not teach fragile X syndrome.

Oostra et al. teach fragile X syndrome.

It would have been obvious to combine the method for analyzing Short Tandem Repeat Polymorphism (STRP) markers of Beattie et al. with fragile X syndrome of Oostra et al. because Oostra et al. teach that fragile X syndrome results from the expansion of the highly polymorphic, short, CGG trinucleotide repeat in the 5' untranslated region of the FMR1 gene on the X chromosome (p. 258, col. 2, lines 1-10). The disease is expressed when the CGG repeats expand to >200 repeats that are methylated thereby silencing the expression of the FMR1 gene (p. 258, col. 2, last line to p.259, col. 1, lines 1-3).

One would have been motivated to do so because Oostra et al. teach that Fragile X syndrome is the most prevalent causes of heritable mental retardation (p. 257, col1, line 1).

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One would have had a reasonable expectation of success of using the method of Beattie to detect mutations indicative of fragile X syndrome because the method of Beattie et al. directed to analyzing polymorphisms in nucleic acids and is applied to identifying repetitive sequences similar to the repetitive sequences that occur in fragile X syndrome.

No claims allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

KRS

John S. Brusca 2 October 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER